

AMENDED IN SENATE MAY 26, 2006

AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

## ASSEMBLY BILL

**No. 1382**

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**Introduced by Assembly Member Nakanishi**

February 22, 2005

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An act to amend Sections 2540, 2541, 2541.3, 2541.6, and 2543 of the Business and Professions Code, relating to prescription lenses.

### LEGISLATIVE COUNSEL'S DIGEST

AB 1382, as amended, Nakanishi. Prescription lenses.

Existing law requires the State Department of Health Services, the State Board of Optometry, and the Division of Licensing and Division of Medical Quality of the Medical Board of California to prepare and adopt quality standards and adopt regulations relating to prescription ophthalmic devices, including, but not limited to, contact lenses. A violation of these regulations is a misdemeanor.

The existing Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of food, drugs, and cosmetics. *Existing law prohibits a person, other than a physician and surgeon or optometrist from measuring the powers or range of human vision or determining the accommodative and refractive status of the human eye or scope of its functions in general or prescribe ophthalmic contact lenses, or plano contact lenses.*

*This bill would, instead, prohibit a person, other than a physician and surgeon or optometrist from measuring the powers or range of human vision or determining the accommodative and refractive status*

*of the human eye or scope of its functions in general or prescribe ophthalmic devices, as defined.*

*Existing law specifies that a prescription lens is any device ordered by a physician and surgeon or optometrist, that alters or changes the visual powers of the human eye, including, but not limited by, ophthalmic and contact lenses.*

*This bill would, instead, specify that a prescription ophthalmic device includes specified types of contact lenses and plano contact lenses.*

Existing law provides that it is a deceptive marketing practice for any licensed physician and surgeon, licensed optometrist, or registered dispensing optician to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.

~~This bill would expand the scope of this provision by making it a deceptive marketing practice for any person to do these acts also make a deceptive marketing practice for any individual or entity who offers for sale plano contact lenses, as defined, to represent by any means that those lenses may be lawfully obtained without an eye examination or confirmation of a valid prescription, or may be dispensed or furnished to a purchaser without complying with prescribed requirements.~~

Because a violation of regulations related to contact lenses is a crime, this bill would expand the scope of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

- 1     SECTION 1. (a) *The Legislature hereby finds and declares*
- 2     *all of the following:*

1     (1) Current California law is intended to prohibit the sale and  
2 use of “plano contact lenses,” which are zero-powered or  
3 noncorrective contact lenses intended to change the appearance  
4 of the normal eye in decorative fashion, without the required eye  
5 examination, fitting, and confirmation of a valid prescription  
6 from a licensed eye care professional.

7     (2) The Congress of the United States by enactment of Public  
8 Law 109-96 amended the federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. Sec. 360j and following) to classify cosmetic plano  
10 contact lenses as medical devices requiring registration with, an  
11 approval by, the Food and Drug Administration before they may  
12 be lawfully marketed and sold in the United States.

13     (3) In enacting Public Law 109-96 the United States Congress  
14 made it clear that the new law is not intended to preempt or  
15 forestall individual states from enacting and enforcing laws to  
16 restrict the marketing and sale of plano contact lenses, by  
17 requiring an examination, fitting, and confirmation of a valid  
18 prescription.

19     (4) Notwithstanding California and federal laws to the  
20 contrary, unqualified entities persist in marking plano contact  
21 lenses, using the Internet and unlicensed retailers to represent  
22 that these lenses may be lawfully obtained and worn without  
23 examination, fitting, and the issuance of a prescription by a  
24 licensed eye care professional.

25     (5) Studies show that in California these marketing efforts and  
26 representations are directed at minors, especially those with  
27 limited proficiency in English, thereby jeopardizing their eye  
28 health and vision.

29     (b) It is the intent of the Legislature, in acting this measure, to  
30 accomplish all of the following:

31     (1) Clarify the definition of plano contact lenses as  
32 prescription ophthalmic devices under California law.

33     (2) Incorporate the federal definition of all contact lenses as  
34 regulated medical devices.

35     (3) Define as a deceptive marketing practice any  
36 representation by a marketer or seller that a plano contact lens  
37 may be lawfully obtained without an eye examination or  
38 confirmation of a valid prescription, as required by California  
39 law.

1     (4) *Encourage contact lens prescribers, fitters, dispensers, and*  
2     *state enforcement authorities to join in educating California*  
3     *contact lens consumers, especially minors, of the dangers to eye*  
4     *health and vision of purchasing and using plano contact lenses*  
5     *unlawfully.*

6     SEC. 2. *Section 2540 of the Business and Professions Code is*  
7     *amended to read:*

8     2540. No person other than a physician and surgeon or  
9     optometrist may measure the powers or range of human vision or  
10    determine the accommodative and refractive status of the human  
11    eye or the scope of its functions in general or prescribe  
12    ~~ophthalmic or contact lenses, or plano contact lenses devices.~~

13    SEC. 3. *Section 2541 of the Business and Professions Code is*  
14    *amended to read:*

15    2541. ~~A prescription lens is any device~~ *ophthalmic device*  
16    *includes each of the following:*

17    (a) ~~Any spectacle or contact lens ordered by a physician and~~  
18    ~~surgeon or optometrist, that alters or changes the visual powers~~  
19    ~~of the human eye, including, but not limited to, ophthalmic and~~  
20    ~~contact lenses. A prescription lens also includes a plano contact~~  
21    ~~lens.~~

22    (b) *Any contact lens described in paragraph (1) of subdivision*  
23    *(n) of Section 520 of the federal Food, Drug, and Cosmetic Act*  
24    *(21 U.S.C. Sec. 360j and following).*

25    (c) *Any plano (zero-power noncorrective) contact lens*  
26    *intended to change the appearance of the normal eye in*  
27    *decorative fashion that is marketed or offered for sale in this*  
28    *state.*

29    SECTION 1.

30    SEC. 4. *Section 2541.3 of the Business and Professions Code*  
31    *is amended to read:*

32    2541.3. (a) The State Department of Health Services, the  
33    State Board of Optometry and the Division of Licensing and  
34    Division of Medical Quality of the Medical Board of California  
35    shall prepare and adopt quality standards and adopt regulations  
36    relating to prescription ophthalmic devices, including, but not  
37    limited to, lenses, frames, and contact lenses. In promulgating  
38    these rules and regulations, the department and the boards shall  
39    adopt the current standards of the American National Standards  
40    Institute regarding ophthalmic materials. Nothing in this section

1 shall prohibit the department and the boards from jointly  
2 adopting subsequent standards that are equivalent or more  
3 stringent than the current standards of the American National  
4 Standards Institute regarding ophthalmic materials.

5 (b) No individual or group that deals with prescription  
6 ophthalmic devices, including, but not limited to, distributors,  
7 dispensers, manufacturers, laboratories, optometrists, or  
8 ophthalmologists shall sell, dispense, or furnish any prescription  
9 ophthalmic device that does not meet the minimum standards set  
10 by the State Department of Health Services, the State Board of  
11 Optometry, or the Division of Licensing and Division of Medical  
12 Quality of the Medical Board of California.

13 (c) Any violation of the regulations adopted by the State  
14 Department of Health Services, the State Board of Optometry, or  
15 the Division of Licensing and Division of Medical Quality of the  
16 Medical Board of California pursuant to this section shall be a  
17 misdemeanor.

18 (d) Any optometrist, ophthalmologist, or dispensing optician  
19 who violates the regulations adopted by the State Department of  
20 Health Services, the State Board of Optometry, or the Division of  
21 Licensing and Division of Medical Quality of the Medical Board  
22 of California pursuant to this section shall be subject to  
23 disciplinary action by his or her licensing board.

24 (e) The State Board of Optometry or the Division of Licensing  
25 and Division of Medical Quality of the Medical Board of  
26 California may send any prescription ophthalmic device to the  
27 State Department of Health Services for testing as to whether or  
28 not the device meets established standards adopted pursuant to  
29 this section, which testing shall take precedence over any other  
30 prescription ophthalmic device testing being conducted by the  
31 department. The department may conduct the testing in its own  
32 facilities or may contract with any other facility to conduct the  
33 testing.

34 ~~SEC. 2.~~

35 *SEC. 5.* Section 2541.6 of the Business and Professions Code  
36 is amended to read:

37 2541.6. No prescription ophthalmic device that does not meet  
38 the standards adopted by the State Department of Health  
39 Services, the State Board of Optometry, or the Division of  
40 Licensing and Division of Medical Quality of the Medical Board

1 of California under Section 2541.3 shall be purchased with state  
2 funds.

3 ~~SEC. 3.~~

4 *SEC. 6.* Section 2543 of the Business and Professions Code is  
5 amended to read:

6 2543. (a) Except as provided in the Nonresident Contact  
7 Lens Seller Registration Act (Chapter 5.45 (commencing with  
8 Section 2546), the right to dispense, sell or furnish prescription  
9 ~~lenses~~ *ophthalmic devices* at retail or to the person named in a  
10 prescription is limited exclusively to licensed physicians and  
11 surgeons, licensed optometrists, and registered dispensing  
12 opticians as provided in this division. This section shall not be  
13 construed to affect licensing requirements pursuant to Section  
14 111615 of the Health and Safety Code.

15 (b) It shall be considered a deceptive marketing practice ~~for~~  
16 ~~any person to publish or cause to be published any advertisement~~  
17 ~~or sales presentation relating to contact lenses representing that~~  
18 ~~contact lenses may be obtained without confirmation of a valid~~  
19 ~~prescription. for:~~

20 (1) *Any licensed physician and surgeon, licensed optometrist,*  
21 *or registered dispensing optician to publish or cause to be*  
22 *published any advertisement or sales presentation relating to*  
23 *contact lenses that represents that contact lenses may be*  
24 *obtained without confirmation of a valid prescription.*

25 (2) *Any individual or entity who offers for sale plano contact*  
26 *lenses, as defined in subdivision (c) of Section 2541, to represent*  
27 *by any means that those lenses may be lawfully obtained without*  
28 *an eye examination or confirmation of a valid prescription, or*  
29 *may be dispensed or furnished to a purchaser without complying*  
30 *with the requirements of Section 2562, except as provided in*  
31 *Chapter 5.45 (commencing with Section 2546).*

32 SEC. 4. No reimbursement is required by this act pursuant to  
33 Section 6 of Article XIII B of the California Constitution because  
34 the only costs that may be incurred by a local agency or school  
35 district will be incurred because this act creates a new crime or  
36 infraction, eliminates a crime or infraction, or changes the  
37 penalty for a crime or infraction, within the meaning of Section  
38 17556 of the Government Code, or changes the definition of a

- 1 crime within the meaning of Section 6 of Article XIII B of the
- 2 California Constitution.

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